



American Bakers Association

Serving the Baking Industry Since 1897

June 20, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004N-0456; Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes
(70 Federal Register 17010 (April 4, 2005))

Dear Sir/Madam:

These comments are submitted on behalf of the members of three separate organizations with similar over-arching missions, the American Bakers Association (ABA), The Grain Foods Foundation (GFF) and the Wheat Foods Council (WFC). Between the three organizations, we represent the majority of U.S. grain producers, bakers and allied trades in the grain foods industry. The ABA, GFF and WFC and their members share FDA's goal of providing consumers with accurate, truthful and non-misleading information regarding serving sizes of a product that can reasonably be consumed at one eating occasion.

Serving Sizes

We believe that the current Nutrition Facts Panel (NFP) is generally straightforward in providing easy to understand information on serving sizes, calories and nutritional information for food products and that they are understood by the majority of American consumers that read nutrition labeling, as illustrated by results of several National Gallup Surveys sponsored by the Wheat Foods Council and the American Bakers Association over the past 10 years. ABA recommends that FDA consider partnering with industry on consumer outreach and education regarding the NFP, and food nutritional labeling in general, which could assist the public in utilizing the NFP and promoting informed, healthy eating choices.

Generally, we believe that consumers do not recognize the difference between serving sizes and recommended servings per USDA/HHS recommended dietary guidance such as the new 2005 Dietary Guidelines for Americans and Food Guidance System. The changes in the new guidelines that recommend, for example 10-one ounce servings of grain based foods daily, is a departure from the six to eleven servings previously recommended. This creates challenges for the average consumer. We have concerns that consumers will have a hard time understanding the concept of grain foods in terms of ounces rather than more conventional household measures. A considerable amount of education is needed to help consumers grasp this new concept. In general, Americans are accustomed to thinking of fluid measure in ounces but not bakery products.

FDA should continue to allow voluntary, but not make mandatory, listing the total number of servings per package on the Principal Display Panel (PDP) to assist consumers in understanding the total number of servings within the whole package and to add emphasis to the servings in a package.

1350 I Street, NW Suite 1290 • Washington, DC 20005 • 202-789-0300 ph • 202-898-1164 fax
www.americanbakers.org

We do not support changing the current wording of “serving” to “recommended amount”. This word change would take up additional space that would be difficult to use on small labels. Further, ABA does not think it would necessarily clarify and provide further meaningful guidance on appropriate consumption levels or positively impact consumers’ eating behavior.

Updating the Reference Amounts Customarily Consumed (RACCs)

We believe that the rationale FDA used to determine the RACCs in its December 28, 1992 final Nutrition Education and Labeling Act (NLEA) regulation establishing serving sizes and serving size labeling requirements for food still generally applies today and should not be changed. Previously, the American Bakers Association put much time and effort into making recommendations to FDA on a variety of bakery products. All but one of those recommendations, serving size for fruitcake, is still applicable today. In the case of fruitcake, we believe that the current four ounce serving is not customarily consumed by the general public. We believe strongly that a two ounce serving would be more appropriate.

The Nutrition Labeling and Education Act (NLEA) states that the Agency needs to provide good guidance to consumers on healthy eating patterns. Ideally, the serving sizes should align with current Dietary Guidance, such as the 2005 Dietary Guidelines and Food Guidance System. We think that the Agency should leverage the food label as a tool to provide guidance on the appropriate amount of food to eat. However, if FDA were to update the RACCs using current consumption data, it would find that consumers are eating more than ever before, in larger portions resulting in increased consumption patterns. To encourage this type of behavior will not promote health, but in fact is likely to be counterproductive and fuel the current trends of over-consumption.

A recent Centers for Disease Control and Prevention (CDC) Report, “*Overweight and Obesity: Clearing the Confusion*”, states that over the past 20 years, the rates of obesity and overweight in this country have soared astronomically. In some states, more than 25 percent of the population is considered obese. Overall, as a nation, 65 percent of adults are overweight and approximately 30 percent of adults meet the criteria for obesity. Additionally, the CDC report says that 16 percent of the nation’s children are obese and that number has increased two-fold over the past 20 years. For this reason, ABA thinks it would be highly irresponsible for FDA to consider increasing the RACCs and serving sizes to reflect current consumption.

It would logically follow that if FDA were to increase the serving size on food labels, consumers would be influenced to think it would be acceptable to eat a larger portion of the food product. In effect, it would give consumers permission to eat more, and ABA does not believe that it is FDA’s intent to encourage dietary patterns that would promote consumption of larger portions based on the public health concern of the growing obesity epidemic. FDA, of course will want to parallel its regulations and guidance with the recently released 2005 Dietary Guidelines and Food Guidance System, which would be in complete conflict with increased serving sizes and RACCs. Further, the Federal Food Drug and Cosmetic Act (FD&C Act) prohibits false and misleading labeling, and we believe that increasing the RACCs and subsequently the serving sizes, would be very misleading and potentially harmful to public health.

FDA may want to consult with and give consideration to the USDA’s Agricultural Research Service (ARS) Food Surveys Research Group (FSRG) that has developed a new method for achieving what has been described as an almost perfect recall of consumption. Work began in 2002 on an innovative survey instrument, the Automated Multiple Pass Method (AMPM), which assists people in reporting the foods they consumed over a 24 hour period. The AMPM validation study has created a large database on diet, energy expenditure, weight status, body composition, physical activity, fitness and biochemical indices of diet and health based on 525 adult participants. We believe that this new innovative approach has

significant merit and should be given further consideration as a consumption survey tool as it provides an overall picture of health and consumption.

Single-Serving Containers

Currently, the baking industry has single serve and snack portions that are considered reasonable to consume in a single eating occasion. Some of these are one serving, while others may be two or three servings. In these cases, the serving size and nutritional information are listed on the package and fully disclose to consumers the serving size, calories and nutritional information regarding the specific product they are consuming. For some packaging, it could be logical to have dual side-by-side labels that compare the entire package and one serving. In other cases, the side-by-side comparison could be more meaningful for displaying the nutrition information for a common weight of food; this may help consumers compare foods more effectively. Side-by-side labeling would require plate changes that could cost a significant amount of money for companies with a large number of skus, would use up valuable package space that often is used for other types of nutritional education messages and would be difficult to add to small packages.

If FDA proceeds with moving forward with dual side-by-side labeling, we strongly think it should be done on a voluntary basis and not made mandatory.

ABA believes that the current rules for single servings is confusing and may promote over consumption. Consumers need clarity and consistence among all packages and package sizes regardless of the count. If FDA wants to encourage healthy eating amounts and patterns, would it really assist individuals to be told the entire package is one serving? The labeling rules for single servings need to be re-written to promote clarity, consistency and comprehension for consumers.

As ABA has commented in the past, we do not believe that use of percent Daily Value labeling is understood or is useful to the average consumer. We are opposed to listing the Percent Daily Value for serving information for the same reasons that we opposed it last year when commenting on *trans fatty acid* labeling in ABA's April 15, 2004 comments (Docket No. 2003N-0076) and most recently when we opposed it in our June 14, 2005 comments for use in reference to calories consumed (Docket No. 2004N-0463). In its 2004 comments, ABA noted:

"As part of its plan, FDA should additionally review consumer's' understanding of the daily value (DV) concept and whether it is used and effectively understood by consumers to gain the nutritional information they seek when making food choices. Current data reveals that use of the percent DV listing in the nutrition facts panel is questionable at best. The majority of consumers who use the nutrition facts panel, in food purchase decisions, use quantitative amount declarations. A Year 2000 study by Lisa Levy and co-workers, cited in the IOM/NAS 2003 Guidance Report (page 2-15), indicates that the majority of test subjects could not define %DV and did not find it useful for assessing the fat content of a product or how to use it to appropriately select a diet low in fat. Additionally, FDA's own research in the "Calories Count" Report of the Working Group on Obesity (2004) finds that "(V)ery few participants reported using the %DV column on the Nutrition Facts Panel. Either they did not understand the meaning of %DV, or they thought that it was not relevant to them since they did not consume a 2000 calorie diet."

Further, there is no government legal mandate for DV's for all nutrients to be listed in the nutrition facts panel. The Nutrition Labeling and Education Act (NLEA) (21 U.S.C. §343) does mandate that FDA devise a label format to serve two purposes: 1) to allow product to product comparisons, and 2) to allow consumers to make judgments about how a single product fits into

the diet. However, it does not mandate that the label alone provide complete dietary guidance and require use of the percent DV format. Certainly, there is no mandate for adoption of a DV without a scientific basis. There are other nutrients, for example sugars, for which FDA has not adopted a DV.

However, if the Agency chooses to proceed, it should develop a clear, comprehensive educational plan on DV before advancing this concept to the public. It would be premature for the Agency to adopt a DV for *trans* fat without key educational components being in place; without that foundation, ABA would question the public health benefit to such a labeling change.”

ABA continues to believe that these arguments apply also for %DV for servings and single servings of a particular food since there is no science to back up such a determination and consumers do not understand this concept.

Comparison of Calories in Foods of Different Portion Sizes

ABA believes it would be confusing to consumers to have claims made only on the basis of the difference in the amount of calories in two different labeled servings or two different portions and would serve no constructive purpose, rather it could confuse consumers. ABA recommends that FDA not change labeling policy on claims.

As FDA has noted, currently all comparative calories claims are limited to reductions of at least 25 percent. For bakery products, which tend to have low calorie levels, ABA believes that limits in reduction of 25 percent are meaningful and reasonable. If a 100 calorie bakery product reduced it calories by 10%, for example, there would only be a 10 calorie reduction, which is insignificant. Lastly, ABA suggests that FDA regulated packages should not be permitted to declare fractional servings. However, FDA should recognize that sometimes product weights and RACC’s do not calculate exactly, therefore, ABA would want to retain the use of the word “about” in such cases.

Costs to Industry

Opening of the RACCs and serving sizes would require changing all of the packaging for the entire foods industry. FDA should carefully weigh the public health benefit and merit of undertaking such a large and costly change. Many large baking companies have an average of 2,000 skus. To change the font size or to bold print on the label would require a change in electronic art, feeding all the way through to a new printing plate for every product. The cost for this exercise would range from approximately \$500 - \$3000 per sku. For a large company, such changes would cost well in excess of \$1 million. Further, there are additional costs associated with packaging that must be destroyed because it has become obsolete. Would such a change positively impact public health in such a way as to justify the enormous undertaking for both the industry to implement and for the Agency to enforce? Has FDA considered the resources needed to adequately educate the public on new nutrition labeling schemes, train inspection staff on such new regulations and enforce compliance with industry?

Currently regulations allow Congress and FDA to give manufacturers only a minimum of twelve months notification to make labeling changes before a compliance date takes affect. FDA should consider other future labeling changes that may be required of industry and work to coordinate such changes in a more efficient and cost saving manner; perhaps making uniform compliance dates every five years rather than the current two.

ABA, GFF and the WFC appreciate this opportunity to comment on this advanced notice of proposed rulemaking, which is of great interest to the grain foods industry. Our organizations are
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www.americanbakers.org

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hopeful that the concerns outlined above regarding a variety of issues relating to serving sizes will be useful to the Agency as it moves forward to establish further policy. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



Lee Sanders
ABA Vice President
Regulatory & Technical Services



Paul C. Abenante
ABA President & CEO



Judi Adams, MS, RD
GFF President



Marcia Scheideman, MS, RD, CFCS
WFC President